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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,623	09/20/2005	Hiroyuki Sugawara	1034509-000001	8092

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EXAMINER

CECIL, TERRY K

ART UNIT	PAPER NUMBER
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1797

NOTIFICATION DATE	DELIVERY MODE
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02/19/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com
offserv@bipc.com

Office Action Summary	Application No. 10/549,623	Applicant(s) SUGAWARA ET AL.	
	Examiner Mr. Terry K. Cecil	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-8,11-16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) 8,11-14 and 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

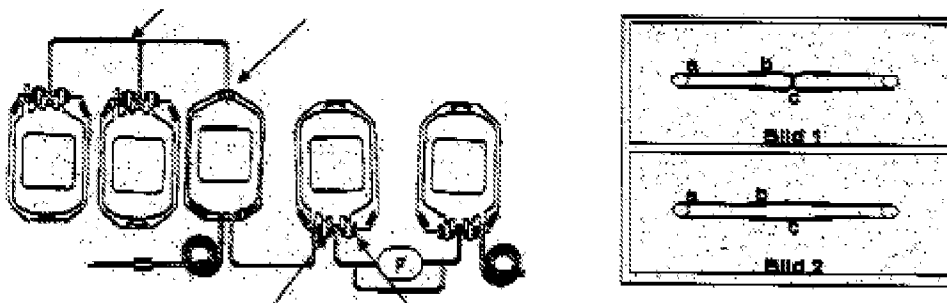
- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group 1 (claims 1-2, 5-7, and 15-16) in the reply filed on 10-22-2009 is acknowledged. The traversal is on the grounds that all claims can be searched without serious burden since all the claims of this application have already been made in the first office action. This is not found persuasive because the method claims added in the amendment of 6-3-2009 have not been searched (a method invention has not been searched). It is contended that searching the method with the apparatus would be a serious burden. It is also pointed out that unity is lacking between the groups as shown in the restriction requirement. The requirement is still deemed proper and is therefore made FINAL. Claims 8, 11-14 and 18-21 are withdrawn.

Claim Rejections - 35 USC § 102

2. Claims 1-2, 6-7 and 15-16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over DE 10019985A1, hereinafter '985.



'985 teaches all the limitations of claims 1 and 15 geared to the end product of the blood treating set having a blood collecting device including a first bag (center bag) and a first tube (connected and extending to the right side thereof) and having a blood treating device including a second

Art Unit: 1797

bag (the rightmost bag) and a second tube including a filter (F) midway or intermediate thereof.

As shown in figure 3, the arrows denote “areas of application” that include the connections shown in figures 1 and 2.

Claims 1 and 15 also include limitations geared to product-by-product limitations or “intermediate” products of the process to make the cell set. For example, the tubes being “aseptically connected” together is a product-by-process limitation and the indications which exist on the tube before the tubes are connected are considered to describe an intermediate state of the product during the process to create it. However, it is pointed out that “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the [end] product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Nevertheless, it is pointed out that the connection including the releasable valve prevents contamination (page 3 of the English translation) and that the ends of the larger diameter tube “b” and the area therebetween can be considered the connection indications or region [as in claims 2 and 16]. It is contended that the end product of the '985 set is the same as that of the Applicant's and that any difference is considered to have been obvious.

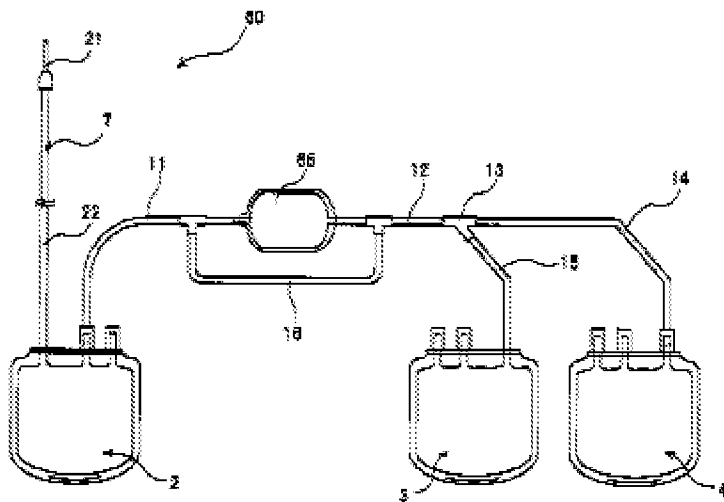
After connection, the lengths of the tube are considered to be “substantially constant” in that they are not extendable. In Applicant's specification he uses the phrase to describe the relationship

Art Unit: 1797

among a plurality of created sets. However, since only one set is claimed, such an interpretation would be irrelevant. It is contended that Applicant's described invention is more conducive to the non-elected method of making invention.

As for claim 6, the treating device includes another bag (second from the right in figure 3). As for claim 7, the treating device is "operative" (can be used) in centrifugation and recovery of blood components (see page 3 of the blood treatment device).

3. Claims 1-2, 5-7 and 15-16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over JP2001- 276212, hereinafter '212.



'212 also teachings the claimed limitations of the blood set end product including the first bag 2 and first tube 11 (between the bag and the first three-way connector/cock); and second bag (3, 4) and second tube (between the first two three-way connector/cocks) having a leukocyte filter 65 midway/intermediate therebetween. See the comments above concerning the product-by-process

Art Unit: 1797

limitations and those geared to intermediate products. However, '212 teaches the tubes to be aseptically connected (see page 26 of the English translation); and also the ends of the three-way connector/cocks can be considered connection indicators.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-2, 5-7 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over '212 in view of JP 2000-046257, hereinafter '257. Alternately, '257 teaches the claimed tube connection indicators. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the indications of '257 on the tubes of '212 since '257 teaches the benefit of a worker confirming that the pipes are completely connected.

Response to Arguments

6. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection. However, it is contended that Applicant's described invention is more conducive to the non-elected method of making invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1797

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Terry K. Cecil whose telephone number is (571) 272-1138.

The examiner can normally be reached on 8:00a-4:30p M-F..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on (571) 272-1166. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mr. Terry K. Cecil/
Primary Examiner, Art Unit 1797

tkc